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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,988	02/11/2004	Timothy J. Guzi	OC01617K1	5341

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SCHERING-PLOUGH CORPORATION  
PATENT DEPARTMENT (K-6-1, 1990)  
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EXAMINER

MCKENZIE, THOMAS C

ART UNIT PAPER NUMBER

1624

DATE MAILED: 01/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 10/776,988	<b>Applicant(s)</b> GUZI ET AL.	
	<b>Examiner</b> Thomas McKenzie, Ph.D.	<b>Art Unit</b> 1624	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 16 December 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.

6. ☒ Newly proposed or amended claim(s) 44-47, 49, 50 and 52-54 would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 44-47, 49, 50 and 52-54.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 31-43, 48, 51 and 55-70.


Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☒ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
 12. ☒ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). 573/05  
 13. ☐ Other: \_\_\_\_\_.

  
 Thomas C. McKenzie, Ph.D.  
 Primary Examiner  
 Art Unit: 1624

Continuation of 11. does NOT place the application in condition for allowance because: Claims 32-36, 38-40, 55, 56, 58, 59, 62, and 63 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The specification does not set forth any steps involved in determining how to identify what diseases and treatments applicant is intending to encompass so that "the therapeutically effective amount of at least one compound of claim 1" could be determined, who is "a patient in need of" "inhibiting one or more cyclin dependant kinases", or which diseases are "associated with a kinase".

Applicants make the argument trhat their proposed amendments will overcome this rejection. However, the claims are clearly directed to disease treatment. Claim 33 uses the word diseases and claim 34 uses the word treatment. Only patients have compounds administered to them as required by claim 32. However, Applicants' will not, or cannot, tell us what diseases are to be treated. Without such information a potential infringer would have no clue as to the metes and bounds of the claims.

Claims 32-42 and 55-70 remain rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for treating any human disease. The specification does not enable any physician skilled in the art of medicine, to make the invention commensurate in scope with claims 32-40 and 55-70 or to use claims 41 and 42.

Applicants make the argument that their 132 declaration provides the enablement for disease treatment. The declaration was not timely filed and the declaration fails to establish any nexus between the ability of compounds to inhibit the CDK1 enzyme and clinical efficacy for the treatment of any disease.

Claims 31-43, 48, 51, and 55-70 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19, 21-47 of copending Application No. 10/654,546. Although the conflicting claims are not identical, they are not patentably distinct from each other because there are many identical or obvious species in these two sets of claims. For example the species of the present claim 48 is found in racemic form in the upper left hand corned of page 19 of the recent amendments to copending Application No. 10/654,546. For examples the species of the present claim 51 is an obvious N-oxide of the species in the upper right hand corner of page claim 27 of the recent amendment to copending Application No. 10/654,546. Line 9, page 4 of copending Application No. 10/654,546 teaches the equivalence of N-oxides and reduced forms of heteroaryl radicals. Additionally, the species in the middle of the last row in page 3 the present recent amendments is an obvious homologue of the species in the lower right hand corner of page claim 18 of the recent amendments to copending Application No. 10/654,546. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. Applicants' request to have this provisional rejection held in abeyance is noted.